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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,045	08/31/2001	Masahiro Sasaki	188-88	7829

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,045	SASAKI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2004 and 23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29-32 and 34-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,29-32 and 34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2004 has been entered.

Claims 21, and 31 have been amended. Claims 21-27, 29-32, 34-39 are pending and examined on merits.

This Office action contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Maintained

Claims 21-32, and 34-39 remain rejected under 35 U.S.C. **102(b)** as being anticipated by JP 1-256351 (I989, IDS).

Claims 21-32, and 34-39 are interpreted as drawn to composition suitable for oral administration comprising water-soluble sericin mixture per se, wherein

claim 22-24, 26, 36, 38, and 39 list the characteristics of the active ingredient of said composition, wherein claim 25, 32, and 35 list other ingredients in said composition, wherein claim 27 lists an intended use i.e., "in the form of a health supplement", wherein claim 29, 34 list the dose ranges, wherein claim 30, 37 list the source of sericin.

Applicant argues that an average molecular weight of sericin used in JP 1-256351 is only 3000, clearly outside of the claimed range, i.e. between 20,000 and 100,000 (the Office assumes that "10,000" in line 3 from the bottom of page 6 under "REMARKS" because the claims are drawn to molecular weight of "20,000 and 100,1000"). This conclusion appears to be based on a statement made by one of the inventor in the Japanese patent. Applicant also argues that the chemical or physical structure of the gelled final product and the instantly claimed invention are different because soluble, not gels. The arguments have been fully considered but found unpersuasive for the following reasons.

Applicant argument with mere uncorroborated hearsay or rumor by the inventor of the Japanese patent does not constitute substantial evidence. See Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229-30 (1938). The statement of facts must be signed, where at all possible, by a person having firsthand knowledge of the facts recited therein. Copies of documentary evidence such as declaration under 37 CFR 1.132 including a statement of facts, or scientific evidence is necessary in order to evaluate whether the composition of the prior art does not possess the same material, structural and functional characteristics

of the instantly claimed composition. It is important that the statement contain facts as opposed to conclusions.

Further, in order to be an art, the final product of the art does not have to be same as the instantly claimed invention. Intermediate product on its way to the final product is also an art as long as it possesses possess the same material, structural and functional characteristics of the instantly claimed composition. As stated in the previous Action, the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989JP 1-256351 thus anticipates the instantly claimed invention.

Claims 21-32, and 34-39 remain under 35 U.S.C. **102(e)** as being anticipated by US Pat. 6,165,982 (Yamada et al) is applied to new claims 21- 39 and maintained.

Claims 21-32, and 34-39 are interpreted as drawn to composition suitable for oral administration comprising water-soluble sericin mixture per se, wherein claim 22-24,.26, 36, 38, and 39 list the characteristics of the active ingredient of

said composition, wherein claim 25, 32, and 35 list other ingredients in said composition, wherein claim 27 lists an intended use i.e., "in the form of a health supplement", wherein claims 29, and 34 list the dose ranges, wherein claim 30, 37 list the source of sericin,

Applicant argues that Yamada et al fails to discloses "effective amount" of sericin. The argument has been fully considered but found unpersuasive because the claims are interpreted as drawn to composition per se derived from silkworm cocoons or raw silk and the intended use is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition *per se*, whose main ingredient is sericin mixture from silkworm cocoons or thread.

As for arguing with the limitation in claims 29, and 34, the dose is not dosage being administered to a patient but the composition is in such a way that it could be administered with such dosage. Therefore, with regards to claims 29, and 34 in which optimum parameters and/or control measurements are claimed, it is well within the level of ordinary skill in the art to adjust optimum concentrations of each components for specific intended uses. See In re Kronig, 190 USPQ 425.

US Pat. 6,165,982 teaches composition suitable for oral administration comprising sericin derived from silkworm cocoons or raw silk. See columns 4-6, and claims 4-15.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 21-27, 29-32, and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-27, 29-32, and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: an unit of the "molecular weight range between 20,000 and 100,1000" in base claims 21, and 31. Is it kg, g, mg, or Daltons?

Regarding claims 25, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 21-27, 29, 30, and 36 provide for "in an effective amount to prevent colon cancer", but since the claim does not set forth any steps involved in the method/process of preventing cancer, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites "to prevent" without any active, positive steps delimiting how this use is actually practiced.

Claims 21-27 are rejected under 35 U.S.C. 101 because the claimed recitation of "to prevent colon cancer", without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 21-27, 29-32, and 34-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is made because of the limitation "an average molecular weight range between 20,000 and 100,1000" in base claims 21, and 31. The new limitation was introduced in the claims with the amendment filed on 1/29/2004. The specification as originally filed at page 9 has support for making sericin of an average molecular weight of either 100,100 or 20,000 but does not appear to have support for "range between 20,000 and 100,1000".

Conclusion

All other rejection set forth in the previous Office action but not repeated is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642